

# CONSUMER UNDERSTANDING AND IMPLICATIONS OF MODIFIED RISK INFORMATION IN A WARNING LABEL



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# OUTLINE

- Section 911 requirements related to consumer understanding of modified risk information
- Overview of SMNA's Consumer Perception Study
- Discussion of the implications of modified risk information in the context of a warning label

# SECTION 911 REQUIREMENTS RELATED TO CONSUMER UNDERSTANDING OF MODIFIED RISK INFORMATION

# SECTION 911 REQUIREMENTS RELATED TO CONSUMER UNDERSTANDING OF MODIFIED RISK INFORMATION

Section 911(h)(1) of the FD&C Act requires that “any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the disease and health-related conditions associated with the use of tobacco products.”

# OVERVIEW OF SMNA'S CONSUMER PERCEPTION STUDY

# SMNA'S CONSUMER PERCEPTION STUDY: OVERVIEW OF STUDY DESIGN AND METHOD

- Online experimental study with internet consumer panel
- Sample: U.S. adults (N = 13,203) ages 18 and older
  - Current tobacco users (n = 6,593), defined as those who identified as daily users of any tobacco product (or NRT); and
  - Non-users (n = 6,610), including both former and never tobacco users.
- Participants randomly assigned to view one of six warning labels (WL):
  - 4 current warnings for smokeless tobacco
  - 1 proposed modified risk label, per the application: "Warning: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes."
  - 1 alternate modified risk label ("lower risk").
- Design: 2 (Tobacco use: Current User vs. Non-User) x 6 (WL: 4 current WLs, 2 modified risk labels) between-subjects experimental design.



# SMNA'S CONSUMER PERCEPTION STUDY: OVERVIEW OF STUDY DESIGN AND METHOD

Per the applications (p.689), the study was intended to assess “the effect of marketing the Snus Products with a modified warning label on the following populations and behaviors” including:

- Tobacco use behavior\* among current users;
- Tobacco use initiation behavior\* among non-users;
- Consumer understanding and perceptions of the product;
- The population as a whole.

\*Note: Behavior was not directly assessed or observed in this study. Thus, statements regarding “tobacco use behavior” pertain to items assessing participants’ stated intentions: e.g., reported likelihood to use the product.

# SMNA'S CONSUMER PERCEPTION STUDY: APPLICANT CONCLUSIONS

- Study results are provided in an appendix to the applications: “Premarket Consumer Research Report” (589 slides).
- Findings are summarized and conclusions are reported by topic and by subgroup, across 13 pages in the application narrative (p. 691-704).
- The summary of results does not correspond to a set of pre-specified hypotheses.

# SMNA'S CONSUMER PERCEPTION STUDY: APPLICANT CONCLUSIONS: UNDERSTANDING

SMNA Concluded (p.696): “In sum, **while most of the total respondents**, current users and current non-users of tobacco **found the modified risk claims to be understandable and clear**, these results were significantly lower than those reported for the current warnings.”

- Results (Slides 13-14) : Compared to participants who viewed the current warnings, fewer participants who saw the modified risk label reported it was understandable and clear.

# SMNA'S CONSUMER PERCEPTION STUDY: APPLICANT CONCLUSIONS: PERCEPTIONS OF HARM

SMNA Concluded (p. 696): “**Significantly more of those exposed to the modified risk claim rated snus as somewhat less harmful than cigarettes** compared to those exposed to the current claims, significantly more of whom reported that cigarettes and snus are equally harmful.”

- Results (Slide 21): Significantly more participants who saw the modified label rated snus as “somewhat less harmful” than cigarettes compared to those who saw the current warnings. Likewise, fewer participants in the modified risk condition said that snus was “much more harmful” than cigarettes compared to those in the current warning label conditions.

# SMNA'S CONSUMER PERCEPTION STUDY: APPLICANT CONCLUSIONS: CURRENT USERS

SMNA Concluded (p. 693): “In sum, the modified risk claims resulted in **a modest increase in the likelihood that current tobacco users would use or purchase snus**, and **a minimal increase in the likelihood that they would engage in dual use of both cigarettes and snus**. The modified risk claims also increased the likelihood that imminent quitters and reducers would be more likely to use, more motivate to buy, and less likely to be discouraged from using snus. A quarter (25%) of the imminent quitters who were likely to use snus reported that they were likely to be dual users of snus and cigarettes, and most of those reported that they would use snus to reduce or quit cigarettes.”

- Results (Slide 61, 71): Relative to current users who viewed the current warnings, more current users who viewed the modified risk label indicated they were likely to use or purchase snus.
- Results (Slide 62): Among current users who reported they were likely to use the product, more participants who saw the modified risk label reported they would be likely to use snus in addition to cigarettes compared to those in two of the current warning conditions.

# SMNA'S CONSUMER PERCEPTION STUDY: APPLICANT CONCLUSIONS: NON-USERS

SMNA Conclusion (p. 694): **“In sum, the modified risk claims were no more likely than the current claims to encourage nonusers of tobacco to use or buy snus. Although, the current claims were more likely than the modified risk claims to deter snus use among non-users of tobacco, more of those exposed to the modified risk claims reported that the claims were not likely to impact their decision to buy snus.”**

- Results (Slide 113-114): Non-users who saw the modified risk label were no more likely to say they were likely to use (or buy) the product compared to those in the current warning label conditions. However, fewer non-users who saw the modified risk label said they were not likely to use (or buy) the product, compared to those who saw the current warnings.

# SMNA'S CONSUMER PERCEPTION STUDY: SELECT STUDY LIMITATIONS

## Measurement

- The applicant developed its own measures, rather than drawing from the literature.
- Problems with conceptualization, question wording, and response scales compromise the validity of the data.

## Stimuli

- Inconsistencies in wording between the modified risk statement in the application vs. the study stimuli limit applicability of the study data.

## Applicant's Analysis and Interpretation

- The applicant did not provide a statistical analysis plan, *a priori*, to define an analytical approach and criteria for evaluating results and drawing conclusions.
- Lack of a pre-specified analysis plan allows for biases in the interpretation of findings (Ioannidis & Lau, 2003, page 117).

# SMNA'S CONSUMER PERCEPTION STUDY: FDA CONCLUSIONS

- FDA is assessing what conclusions can be drawn from these data regarding consumer understanding of the modified risk label, in light of study limitations, including those discussed in this presentation.



# DISCUSSION OF THE IMPLICATIONS OF MODIFIED RISK INFORMATION IN THE CONTEXT OF A WARNING LABEL

# COMMUNICATION OF MODIFIED RISK INFORMATION IN A WARNING LABEL

- Consumer Perception Study was designed to assess consumers' reactions to the *content* of proposed modified risk label, not the *context* of modified risk information, in terms of whether it is presented:
  - In a warning label vs.
  - In a statement separate from, and in addition to, the warning label.
- Additional questions may be raised by the *context* of that modified risk information: i.e., inclusion of modified risk information in the warning label itself.

# MODIFIED RISK INFORMATION IN A WARNING LABEL: IMPLICATIONS FOR CONSUMER UNDERSTANDING

- Active communication of modified risk information in the context of a government-mandated warning label may raise additional questions regarding:
  - Consumer understanding of that modified risk information;
  - Consumer perceptions of the product;
  - Implications for consumer perceptions of government-mandated warnings on other regulated tobacco products.
- To our knowledge, there is no study that directly examines the effect of the context of modified risk information (in warning label vs. separate from and in addition to a warning label).

# MODIFIED RISK INFORMATION IN A WARNING LABEL: IMPLICATIONS FOR CONSUMER UNDERSTANDING

- Information about relative benefits of product use is atypical for inclusion in a product warning (Wogalter, 2006).
- Language that conveys a relative benefit of product use where consumers expect to see information about potential risks could cause confusion.
- It is unclear if consumers would still perceive this statement as a warning.

# SUMMARY

- The applicant conducted a consumer perception study to assess understanding of modified risk information in the proposed modified label.
- Methodological issues limit the conclusions that can be drawn from these study data.
- However, the context of the modified risk information—conveyed within the warning label—raises additional questions not addressed by the study.
- Inclusion of modified risk information in the warning label raises questions about the implications for consumer understanding and perceptions of tobacco product warning labels.

THANK YOU

QUESTIONS?

